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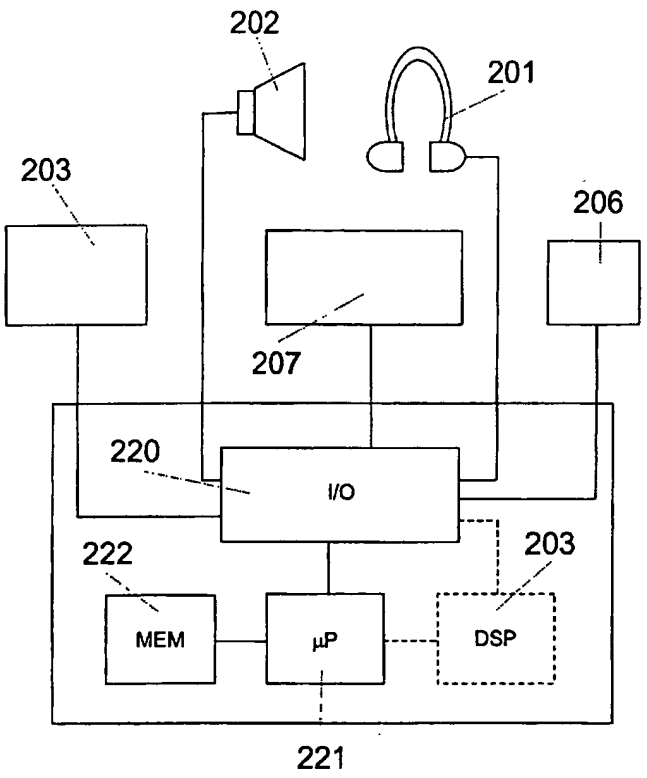
(54) Title: A SYSTEM AND METHODS FOR TREATING PERSISTENT TINNITUS PERCEPTION



(57) Abstract: The present invention relates to a system for treating a patient for persistent tinnitus perception. The system is adapted to generate a predefined acoustic stimuli signal via an acoustic signal source or acoustic signal generator, such as an electro-acoustic transducer. The ear to be treated is intermittently affected with the acoustic signal and hereby the tinnitus is masked during stimuli periods of a first predefined duration which are interspersed with inter-stimuli periods of a second predefined duration. The invention also relates to a method for treating a patient for persistent tinnitus perception.

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A SYSTEM AND METHODS FOR TREATING PERSISTENT TINNITUS PERCEPTION

The present invention relates to a method and an apparatus for treating persistent tinnitus perception.

Tinnitus is a condition in which a person perceives sound, such as ringing, buzzing, whistling, or roaring, not existing as physical sound; i.e. a sound is perceived in the absence of an acoustic stimulus. Tinnitus perception may be lasting for a limited period of time, only, but in more serious cases tinnitus can be persistent and therefore extremely uncomfortable. As a result, in serious cases, the tinnitus may lead to mental and physical disturbances.

In the cases in which the tinnitus perception is found to be associated with different ear-related etiology, a treatment may be directed towards the underlying cause of impairment in so far as it is treatable. In other cases, according to the prior art, the problem of the tinnitus may be alleviated in different ways. For example, it is known to alleviate the tinnitus by masking or downing out the tinnitus with a sound signal supplied to the ear of the patient. The sound signal, i.e. a background noise signal, is continuously supplied to the ear of the patient. The goal of this therapy is to use a masking noise signal having the effect that the patient no longer, or only barely, perceives the tinnitus. Instead, a more pleasant masking noise is audible. In other words, masking of tinnitus is based on alleviating the problem and hereby making the person not focus thereon. Even though the patient has to tolerate the supplied background noise signal, this method has been found useful as the patient is often more tolerant to a tinnitus masking signal than to the tinnitus perception itself.

International patent application WO 90/072251 is an example of a tinnitus masking device for generating an acoustic signal having a sound spectrum adapted to mask the tinnitus of the patient as described above.

Further, according to the prior art, when tinnitus perception appears to be persistent and subjectively classified as severe and disabling, the treatment strategies are aimed directly towards the tinnitus perception itself by utilising a combination of a masker, such as a white noise generator, and the use of tinnitus retraining therapy (TRT); overall referred to as habituation of tinnitus perceptual processes. Tinnitus retraining therapy is a subjective psychological assessment in which counselling is used, and the goal is to make the patient no longer focus on the tinnitus perception and hereby easing the problem. The habituation is caused by neuronal associative mechanisms or slowly changing perceptual processes of learning. In order to achieve useful results, the process of tinnitus retraining therapy is normally performed over a period of 12-18 month including at least 10-15 hours of psychological counselling.

US 6,047,074 to Zoels et al. describes a programmable hearing aid operable in a mode for tinnitus therapy. The hearing aid is able to execute different programs both as a hearing aid and as a tinnitus instrument; i.e. the combination of a tinnitus masker and a hearing aid.

The object of the invention is to provide a method for improving the treatment of tinnitus perception compared to the prior art.

According to the invention, the object is achieved by a method comprising the steps of:

- selecting an ear to be treated, said ear being subjected to tinnitus perception;
- determining the frequency, or frequency range, at which the patient's tinnitus occurs in the selected ear;
- establishing, based on the specific tinnitus frequency, or tinnitus frequency range, an acoustic stimuli signal having a frequency, or frequency range, and an intensity enabling the tinnitus to be masked, and
- intermittently affecting the ear to be treated with the acoustic stimuli signal, where stimuli periods of a first predefined duration are interspersed with inter-stimuli

periods of a second predefined duration.

The invention is based on the fact that tinnitus has been found to be a perception of spontaneously generated neuronal activity, a phenomenon occurring at the level of the central nervous system which has been altered due to neural plasticity. These alternations are most often responsible for the tinnitus itself, with analogous links to the limbic system serving as possible mediators of the emotional response to tinnitus.

It is noted that the above-mentioned stimuli signal is an acoustic signal which after affecting the ear of the patient for a period of time may have the effect of resulting in a period of residual inhibition, i.e. a situation in which tinnitus perception no longer occurs at least for a period of time, or at least for a period in which the tinnitus perception is reduced. The inter-stimuli periods on the other hand are periods including signals which do not lead to residual inhibition. Therefore, in an inter-stimuli period in which residual inhibition is present, the tinnitus may reoccur after a period of time, i.e. when the effect of the stimuli signal is no longer present.

According to the invention, by supplying the patient with an acoustic signal varying periodically between stimuli and inter-stimuli intervals, a controlled hyper-polarisation of certain cells in the thalamus of the patient's brain can be achieved. The method according to the invention has been found to result in persistent or at least prolonged effective results on the treatment effect on patients suffering from persistent tinnitus perception due to the plastic or semi-plastic transformation of the brain cells.

The significant treatment results obtainable by using selective auditory rhythmic inhibition according to the invention may be found in the fact that rule based learning mechanisms are employed. Rule based learning mechanisms tend to be those which process individual features selectively through serial processing in working memory using limited attentional resources. In other words, the brain of the patient learns the rules of suppressing the tinnitus on the basis of the stimuli signal perceived and the

resulting effect on the tinnitus.

As the method according to the invention is based on rule mechanisms, significant treatment results are achieved more rapidly compared to methods of the prior art, i.e. compared to methods based on associative learning mechanisms or slowly changing perceptual processes. For example, compared to the above-mentioned tinnitus retraining therapy, useful results are normally achieved rapidly and typically within less than two months. Further, whereas associative mechanisms require much practice to develop, rules can be constructed in an *ad hoc* manner to produce great immediate changes in performance. Therefore, in addition to the positive results of removing or at least reducing the tinnitus perception of patients, the treatment according to the invention is cost effective due to the reduction of the time needed to perform the treatment, i.e. the treatment is more economic.

Further, patients suffering from persistent tinnitus may also suffer from a pathological degree of depression as a consequence thereof. The depression of these patients is most often removed or at least reduced as a result of the treatment of the tinnitus. As a consequence the method of the invention has an additional positive influence on the patients' well being. Therefore, most often the patients can stop using anti-depressive drugs, or at least reduce the amount of drugs used.

According to a preffered embodiment of the invention, the ear to be treated is selected as the ear in which the tinnitus perception is most dominant. Hereby, the tinnitus may be treated most efficiently. Further, the tinnitus of the ear having the least dominant tinnitus is often removed as a positive side effect when treating the ear in which the tinnitus is most dominant.

According to a preferred embodiment of the invention at least one and preferably a major part or all of the said stimuli periods is/are set to be of a specific duration sufficient for obtaining residual inhibition in the patient and preferably in the range of

1-30 seconds and more preferably in the range of 10-15 seconds. The residual inhibition obtained has been found to have a treating effect on the patient due to the rule mechanisms applied. A duration of 1-30 seconds of the stimuli periods has to be found to give good treatment results. Further, on the one hand, the patient is able to perceive the acoustic signal supplied in stimuli periods of such a duration, and on the other hand, by limiting the duration of the stimuli periods to such a duration, the patient can be supplied with a higher number of stimuli periods in a given period of time being of great importance in practice.

According to another preferred embodiment of the invention the duration of said at least one and preferably a major part or all of the stimuli periods is determined by:

- affecting the ear to be treated with at least one acoustic test signal having a temporally defined test stimuli period and determining the duration of the test stimuli period necessary for obtaining residual inhibition in the patient; and

- setting the duration of said stimuli periods to be equal to or larger than the minimum necessary duration determined using the acoustic test signal.

Hereby, in a relatively simple manner it is ensured that at least some of the stimuli periods have a duration sufficient for obtaining residual inhibition when intermittently affecting the ear the patient with the acoustic signal during treatment. The necessary duration may advantageously be determined prior to performing the actual tinnitus treatment.

Preferably, at least one and preferably a major part or all of the said inter-stimuli periods is/are set to be of a specific duration sufficient for the patient again to perceive the tinnitus within said at least one and preferably a major part or all of the said inter-stimuli periods, preferably within 1 - 30 seconds, and even more preferably in the range of 10-15 seconds. Therefore, prior to applying a stimuli period following an

inter-stimuli period, the residual inhibition which may occur as a result of the acoustic signal applied in the preceding stimuli period may have a specific duration. As a result the patient is enabled to perceive the residual inhibition in a specific period of time, and a duration of 10-20 seconds has been found to give good treatment results.

Preferably, the duration of the residual inhibition obtained in the test stimuli period having said established necessary duration is determined and the duration of at least one and preferably a major part or all of the inter-stimuli periods is set to be longer or equal to the determined duration of the residual inhibition. Hereby, it is ensured that the tinnitus reoccur during some inter-stimuli periods in which residual inhibition has been present. This embodiment has been found to produce good treatment results.

Preferably, at least one and preferably a major part or all of the said inter-stimuli periods is/are set to be of a specific duration sufficient for the patient again to perceive the tinnitus for a given period of time, preferably in the range of 1-30 seconds, and more preferably in the range of 10-15 seconds. Hereby, it is ensured that the patient perceives tinnitus prior to a following stimuli period which has been found to give fine treatment results.

In an expedient embodiment according to the invention, said stimuli frequency or stimuli frequency range is set to be in the range of 0.25-2 octaves below the established tinnitus frequency or tinnitus frequency range, and more preferably approximately half an octave below the established tinnitus frequency or tinnitus frequency range. A stimuli signal having this frequency has been found to result in the desired residual inhibition.

Preferably, the acoustic signal comprises a pure tone signal having a fundamental frequency equal to the stimuli frequency. The acoustic signal may also comprise a noise signal having a centre frequency equal to or at least substantially equal to the determined stimuli frequency and with a band width of preferably one third of an

octave. Such pure tone signals and/or noise signals are preferably used, as these types of signals have been found to produce good treatment results.

The invention also relates to a method for treating a patient for persistent tinnitus perception by intermittently affecting the ear to be treated with an acoustic signal having a predefined stimuli frequency, or stimuli frequency range, and an intensity enabling the tinnitus to be masked, wherein stimuli periods of a first, predefined duration preferably in the range of 1-30 seconds, and more preferably in the range of 10-15 seconds, are interspersed with inter-stimuli periods of a second, predefined duration preferably in the range of 1-30 seconds and more preferably in the range of 10-15 seconds. This is advantageous when the signal to be used when treating a patient is known in advance. The advantages of this method correspond to the advantages mentioned above.

The present invention also relates to a system for treating a patient for persistent tinnitus perception, said system comprising:

- a signal source, such as an electro-acoustic transducer, adapted to affect an ear to be treated with an acoustic signal;

- a storage adapted to contain stimuli signal information;

- a processor, such as a digital signal processor, adapted to, based on said stimuli signal information, intermittently affecting the ear of a patient with an acoustic stimuli signal via said signal source, where stimuli periods of a first predefined duration are interspersed with inter-stimuli periods of a second predefined duration, said stimuli signal having a frequency and an intensity enabling the tinnitus to be masked during said stimuli periods.

As the system is adapted for supplying the patient with an acoustic signal varying periodically between stimuli and inter-stimuli intervals according to the invention, a controlled hyper-polarisation of certain cells in the thalamus of the patients' brain may be achieved. Therefore, the system has been found highly effective when treating patients of persistent tinnitus perception. When treating patients using a system according to the invention, the advantages mentioned in relation to the methods are achieved. In addition the patient may perform a major part of the treatment on her or his own after being given an introduction in operating the system according to the invention.

According to a preferred embodiment, the system is adapted to receive stimuli signal information and to store the received stimuli signal information or information derived therefrom in said storage. Hereby, a user of the system may enter patient specific information which may be used in order to determine the frequency of the stimuli signal to be used during the tinnitus treatment performed.

Preferably, the processor is adapted to generate said acoustic stimuli signal wherein at least one and preferably a major part or all of said stimuli periods have a first, predefined duration preferably in the range of 1-30 seconds and more preferably in the range of 10-15 seconds, which is sufficient to obtain residual inhibition in the patient, and at least one and preferably a major part or all of said inter-stimuli periods have a second, predefined duration, preferably in the range of 1-30 seconds, and more preferably in the range of 10-15 seconds, being sufficient for the patient again to perceive tinnitus. Hereby, it is ensured that at least some stimuli periods are followed by inter-stimuli periods in which residual inhibition occurs.

Preferably, the duration of at least one and preferably a major part or all of the inter-stimuli periods is sufficient for the patient again to perceive the tinnitus for a given period of time. Hereby, it is ensured that the tinnitus perception reoccurs in some inter-stimuli periods which has been found to give good treatment results.

Preferably, the signal source is adapted to emit a pure tone signal having a fundamental frequency equal or substantially equal to the set stimuli frequency and/or noise signal having a centre frequency equal or substantially equal to the set stimuli frequency and a band width of preferably one third of an octave. This is advantageous, as stimuli signals having this frequency have been found to result in the desired residual inhibition.

In an expedient embodiment of the invention, the system is built into a hearing aid. Hereby, patients using hearing aids may easily be affected by the acoustic signal according to the invention, i.e. the treatment or at least a major part thereof may be performed by bringing the hearing aid into a tinnitus treatment mode. Further, the system can be implemented such that major parts of the hearing aid are used for tinnitus treatment, e.g. the signal source, the storage, and the processor. In other words, the hearing aid may be programmed to act as a tinnitus treatment system, also. Therefore, this solution enables a compact tinnitus treatment system or apparatus to be produced in such a way that the additional costs thereto are minimized.

Other features and advantages of the method of the present invention will become apparent from the following description of preferred embodiments, taken in conjunction with the accompanying figures wherein:

Figure 1 is a flow chart of a tinnitus treatment method according to the invention,

Figure 2 is an example of a system according to the invention,

Figure 3 is a first example of an acoustic signal which may be used when treating persistent tinnitus perception according to the invention, and

Figure 4 is a second example of an acoustic signal which may be used when treating persistent tinnitus perception according to the invention.

According to the invention, neuronal residual inhibition may be used as a powerful tool, both for a subjective measure of the dynamic components of subjective tinnitus, but also for the treatment of tinnitus itself. The treatment forces a permanent neuronal plastic transformation to occur and alters the emotional impact of prolonged persistent, subjective tinnitus.

Figure 1 illustrates a method of treating persistent tinnitus according to the invention. In order to specifically apply the treatment to the given patient an initial pre-treatment is performed according to a preferred embodiment of the invention. The initial pre-treatment illustrated in step 100 (INIT.) includes obtaining a pure-tone audiogram according to the prior art. Further, an ear-mould impression is made as it enables an in-the-ear type tinnitus treatment apparatus to be constructed to fit the ear of the patient. An in-the-ear tinnitus treatment apparatus is advantageously used in the treatment as a controlled environment may hereby be achieved; i.e. an acoustic signal to be applied to the patient via the in-the-ear part under controlled conditions. For example, an adequate intensity of the acoustic stimuli signal may be achieved. Further, undesired external acoustic noise may be attenuated or left out by the in-the-ear part, and therefore it may be insured that the treatment is performed under controllable conditions. But it is noted that the treatment may also be performed using other sound generating means if desired, e.g. by use of head phones or even by use of a traditional loudspeaker placed adjacent to the patient. Therefore step 100 may be left out in some embodiments of a method according to the invention. The described parts of step 100 may for example be performed on a first day in a clinic preparing the tinnitus treatment to be performed.

Step 100 may also include the following parts which are advantageously performed when the tinnitus treatment apparatus or tinnitus instrument has been constructed to individually fit the ear of the respective patient or subject using the ear measurements mentioned above, e.g. on a second day in a clinic preparing the tinnitus treatment to be performed. An additional fitting may also be performed in dialogue with the patient if

needed. The user may be given instructions in the correct use of the tinnitus instrument, and further, the patient may be tested to determine whether he/she is found suitable for the tinnitus treatment to be performed. Firstly, a visual inspection of the eardrum and the auditory canal of the patient may be performed, e.g. by use of an otoscope. Secondly, in order to ensure that the treatment is performed correctly, the patient may be tested for being intellectually capable of co-operating the psycho-acoustical test-battery described below. In the case wherein the subject is not found suitable for treatment, the treatment is stopped - otherwise the treatment may be performed as described below. When the patient is found suited for the tinnitus treatment, the sound generating means is placed correctly, i.e. the in-the-ear part is placed in the ear or the headphones are placed on the head of the patient.

Advantageously, the tinnitus treatment is focussed on the ear in which the tinnitus is most dominant. Therefore the patient is preferably interviewed in order to determine the dominant tinnitus side (left side, right side or both sides). In order to validate the determination of the dominant tinnitus side, the patient may be asked to reconsider the dominant tinnitus side in a situation in which a masking of the dominant tinnitus side is performed. For example, the dominant tinnitus side is masked by stimulation with a 1/3 octave narrow band acoustic noise signal at an intensity of 50 dB HL for 1.5 seconds. If the patient still finds the same side to be the dominant tinnitus side, this side is selected to be the target side of the stimulation to be performed in the following, i.e. when recording the so-called tinnitusgram and stimuligram. On the other hand, if the patient cannot decide between left and right one of the sides are selected, i.e. the left side is chosen. In step 100 the selected target side is registered as a so-called TDTL value representing the dominant tinnitus location; e.g. a value representing left, central or right.

Further, in order to prepare the patient for the tinnitus treatment, a demonstration of the tone pitch and the sound intensity is performed in a preferred embodiment of the invention. For example, the tone pitch demonstration may be performed in the

following way. The patient is instructed that he/she will hear two pure tones and that the first tone is dark compared to the second tone which is called bright, i.e. the frequency of the first tone is lower than the frequency of the second tone. The difference is called tone pitch in the following. The demonstration may for example be performed using a 250 Hz pure tone as the first tone. The first tone may for example last for 1.5 seconds and have a predefined intensity. As the second tone a 2000 Hz pure tone may be used and this tone may for example also last for 1.5 seconds and have a predefined intensity. This demonstration is performed in order to ensure that the patient is capable of observing and distinguishing tones of different frequencies. It is noted that other frequencies, durations and intensities may be used for the first and/or the second tone during this tone pitch demonstration, if desired.

The dynamic range of the signals used to affect the ear of the user may be selected in such a way that the following requirements are fulfilled. Firstly, it is of importance that the intensity of the stimuli signal is sufficient high for the patient to hear or register the signal. Secondly, the intensity of the stimuli signal has to be sufficiently high to produce the desired residual inhibition. Thirdly, it is of great importance to protect the patients from signals having an undesired high intensity. Therefore, the intensity level of the acoustic signal used for demonstration and the acoustic stimuli signal used during treatment are both selected to have a predefined value above the hearing level and below the uncomfortable sound level of the patient. Preferably, the acoustic signal used for demonstration and the acoustic stimuli signal used during treatment may both have an intensity which is about one third of the difference between the hearing level and the uncomfortable sound level above the hearing level as this intensity has been found to give good treatment results. But it is noted that the intensities of these signals may have other values as well, if desired.

The sound intensity demonstration may for example be performed in the following way. Firstly the user may be instructed that he/she will hear a first and a second pure tone where the first tone will be lower than the second tone, i.e. the sound intensity of

the first tone is lower than the sound intensity of the second tone. Then the user is subjected to two different 1000 Hz pure tones having a duration of 1.5 seconds, for example. The intensity of the first and the second tone may be 1/4 and 1/2 of the selected dynamic range, respectively. This demonstration is performed in order to ensure that the patient is capable of observing and distinguishing tones having different intensities. Even though the above-mentioned sound signals have been found very useful, it is noted that other frequencies, intensities and durations of one or more of the signals may be used as well, if desired.

In step 101 (TG) the frequency of the tinnitus perceived by the patient is determined. This may be performed by recording or registering a so-called tinnitusgram which is a psycho-acoustic measurement of the tinnitus perception of the patient.For example, the tinnitusgram is obtained by measuring the static characteristics of the tinnitus, i.e. the pitch, the loudness, etc, in order to be able to alter the perception of tinnitus via the efferent auditory pathway of tinnitus. The patient is subjected to a first and a second pure tone signal having different frequencies. The frequencies are selected in such a way that it is found likely that the frequency of the tinnitus is located in the frequency band defined by the two frequencies, i.e. in the frequency band between the two frequencies. The patient is instructed to point out the one of the two tone signals having a frequency making the best match to the frequency of the tinnitus perceived. Based on the answer from the patient, at least one of the frequencies is changed in such a way that the frequency band defined by the two frequencies is narrowed compared to the frequency band previously used. The new frequency values are selected in such a way that the frequency of the tinnitus is still likely to be in the frequency band between the two frequencies. This procedure may be repeated until the tinnitus frequency is determined to be inside a frequency band being sufficiently narrow to define the tinnitus frequency accurately enough for practical use.

In step 102 (SG) a measurement of the relationship between the stimuli and the effect achieved is performed. For example, this may be performed by obtaining a first so-

called stimuligram. The stimuligram is a psycho-acoustic measure of the dynamic component of the tinnitus, or the relation between the duration of the stimuli and the duration of inhibition of tinnitus.

In step 103 (DET) the frequency and the intensity, or level, of the stimuli signal to be used are selected using the value of the tinnitus frequency determined in step 101. The frequency and the intensity of the stimuli signal are selected to enable a masking of the tinnitus when effecting the patient with the acoustic stimuli signal. Furthermore, the frequency and the intensity of the stimuli signal are selected to enable residual inhibition to be obtained when affecting a patient therewith for at period of time. It is noted that residual inhibition may be described as a situation in which tinnitus perception no longer occurs at least for a period of time.

In a preferred embodiment, the stimuli frequency or stimuli frequency range is selected to be non-overlapping with the tinnitus frequency or tinnitus frequency range, e.g. a frequency in the interval between 0.25 and 1 octave below the established tinnitus frequency, which has been found to give the most efficient masking of the tinnitus.. In a preferred embodiment a frequency half an octave below the tinnitus frequency is selected as this frequency has been found to produce good treatment results. Other non-overlapping frequencies both above and below the tinnitus frequency have also been found useful, e.g. half an octave above the tinnitus frequency and one octave below/above the tinnitus frequency. Further, the duration of the stimuli periods and the inter-stimuli periods are also selected in step 103.

In step 104 (TREAT) the treatment of the patient is performed by intermittently affecting the ear to be treated with an acoustic signal having the selected frequency as a dominant frequency. The treatment may be performed for shorter or longer periods of time. In a preffered embodiment, the patient is affected by the acoustic signal for a period of 20-60 minutes, preferably 25-35 minutes such as 30 minutes. Preferably, an apparatus such as a hearing aid may be programmed to perform the treatment, and

hereby the user may perform the treatment on his or her own, when desired. For example, after being instructed in the correct use of the apparatus, the patient may perform a number of treatment sessions each day for a number of days.

In step 105 (EVAL) an evaluation of the treatment results is performed by obtaining a second stimuligram. Hereby, a user such as a medical supervisor is enabled to evaluate the progress of the treatment performed, and the following treatment may be optimised using the knowledge obtained during the evaluation. Then the treatment may be resumed by continuing in step 104, or by continuing in one of the steps 100-103. Preferably, all the steps 101-105 are performed for the new treatment session in order to ensure an optimal effect of the treatment. By continuing in one of the steps 100-103, it is possible to optimise the treatment to the present situation, e.g. by selecting optimal durations of the stimuli periods and/or the inter-stimuli periods. For example, a fine tuning of the frequency of the stimuli acoustic signal may also be performed.

Figure 3 is a first example of an acoustic signal which may be used when treating persistent tinnitus perception according to the invention. The signal shown is a fraction of the signal which may be used and it illustrates the laps of time of the signal. As it can be seen from the figure, the signal used is an intermittent acoustic signal which includes a number of stimuli periods 301, 302, 303 being mutually separated by a number of inter-stimuli periods 305, 306.

In the stimuli periods, the patient is affected with an acoustic signal suitable to produce the masking and the desired residual inhibition. Preferably, the acoustic signal in the stimuli periods 301, 302, 303 comprises a pure tone signal having a fundamental frequency of approximately half an octave below the frequency of the tinnitus perceived by the patient. In another preferred embodiment, the acoustic signal used in the stimuli periods 301, 302, 303 comprises a noise signal having a central frequency equal to or at least substantially equal to the frequency half an octave below the frequency of the tinnitus perceived by the patient. As mentioned above other

frequencies of the stimuli signal may be used as well. The band width of the noise signal is preferably one third of an octave, but noise signals having other band widths may be used as well. Furthermore, the pure tone signal may also be mixed with the noise signal when producing the acoustic signal to be used when stimulating the patient during treatment.

The stimuli periods 301, 302, 303 may be selected to have a specific timely duration sufficient for obtaining residual inhibition. According to a preferred embodiment the duration of the stimuli periods are selected in the range of 1-30 seconds and even more preferably in the range of 10-15 seconds such as 15 seconds. For example, the duration of the stimuli periods 301, 302, 303 is selected by affecting the ear to be treated with at least one acoustic test signal having a temporally defined test stimuli period and determining the duration of the test stimuli periods 301, 302, 303 necessary for obtaining residual inhibition in the patient. The stimuli periods 301, 302, 303 are advantageously set to have a duration equal to or larger than the established duration necessary.

In the inter-stimuli periods 305, 306 the patient should not be affected by an acoustic signal masking the tinnitus and resulting in residual inhibition. Therefore, no acoustic signal is preferably supplied to the patient during inter-stimuli periods, but as an alternative an acoustic signal having a different frequency and/or a sufficient low intensity compared to the acoustic signal in the stimuli period 301 may be used in the inter-stimuli intervals, 302, 303. In a preffered embodiment all the inter-stimuli periods or at least some of the inter-stimuli periods 305, 306 have a duration set to have a specific duration sufficient for the patient again to perceive the tinnitus within the inter-stimuli periods as this has been found to produce very good treatment results. Preferably, the duration of the inter-stimuli periods 305, 306 is selected to be approximately 1-30 seconds, and even more preferably to be approximately 10-15 seconds such as 15 seconds.

The duration of the inter-stimuli periods is advantageously determined prior to performing the actual treatment by affecting the patient with an acoustic test signal equal the to stimuli signal to be used in the stimuli periods 301, 302, 303. By registering the duration of the residual inhibition, e.g. by receiving an input from the user when the tinnitus perception is back to normal, a picture of the duration of the residual inhibition to be expected is obtained. The duration of the inter-stimuli 305, 306 periods may be selected to be greater or equal to the duration of the residual inhibition found during the test performed. Advantageously, the duration of the inter-stimuli 305, 306 is selected to be sufficient for the patient again to perceive the tinnitus for a given period of time, preferably for 1-30 seconds and even more preferably for 10-15 seconds such as 15 seconds.

Figure 4 is a second example of an acoustic signal which may be used when treating persistent tinnitus perception according to the invention. The signal shown is a fraction of the signal which may be used. The signal used is an intermittent acoustic signal which includes a number of stimuli periods 401, 402, 403 being mutually separated by a number of inter-stimuli periods 405, 406. The figure illustrates that the inter-stimuli periods do not have to be of equal duration. In the figure, the duration of the inter-stimuli period 406 exceeds the duration of the inter-stimuli period 405. For example, it may be of interest to change to duration of the inter-stimuli periods during treatment as the duration of residual inhibition is normally increased. Likewise, the duration of the stimuli periods 401, 402, 403 may vary, if desired.

Figure 2 is an example of a system according to the invention. The system or apparatus is adapted for treating a patient for persistent tinnitus perception, and may for example be located in a hearing aid.

According to a preferred embodiment of the invention, the apparatus includes an acoustic signal source 201, 202, such as an electro-acoustic transducer, adapted to affect the ear of a patient with an acoustic signal. The system also includes a storage

or memory 222 (MEN) adapted to contain stimuli signal information such as a representation of a frequency, at which tinnitus perception occurs. Further, the system includes a processor 221, 223, such as a micro-processor (μP) or a digital signal processor (DSP). The processor may be adapted for determining the frequency of the stimuli signal to be used by use of stimuli signal information from the storage 222 and generate the stimuli signal by use of the signal source 201, 202. Hereby, the ear to be treated may intermittently be affected with an acoustic signal having the stimuli frequency as a dominant frequency, having a desired intensity or level, and including stimuli periods of a given duration which are interspersed with inter-stimuli periods of a given duration. In another preferred embodiment of the invention, the memory 222 is adapted to hold stimuli signal information including a representation of the frequency and the intensity of the stimuli signal to be used when treating the patient. Furthermore, the memory 222 may hold a representation of the duration of the stimuli and inter-stimuli intervals to be used when treating the patient for persistent tinnitus perception.

In the preferred embodiment illustrated in figure 2, the system includes a central part 200, such as a computer, to which a number of external devices may be connected. In the shown embodiment, the acoustic signal source in the form of headphones 201 is connected to an input/output interface 220 (I/O) of the central part 200. As illustrated, headphones 201 are advantageously used when affecting a patient with an acoustic signal but other acoustic signal sources may be used as well. It only has to be insured that the characteristics of the acoustic signal affecting the ear of the patient is controllable; i.e. the treatment is performed in a controllable environment. Even though a near the ear stimulation is preferred, a loudspeaker 202 such as a traditional moving-coil loudspeaker may for example also be used as an acoustic signal source; when it is ensured that the patient is not distracted by external noise which may effect the result of the treatment.

The signal to affect the patient is generated by the processor by use of the signal

source. Preferably, the stimuli signal generated is a pure tone signal having a fundamental frequency equal or substantially equal to the set stimuli frequency and/or a noise signal having a centre frequency equal or substantially equal to the set stimuli frequency and a band width of preferably one third of an octave, for example. As described previously, the signal is generated in such a way that the ear of the patient is intermittently affected with a stimuli acoustic signal.

Advantageously, the frequency of the tinnitus perceived by the patient is determined by interactively submitting one or more acoustic signals having different frequencies to the patient, and information about the difference between these frequencies and the tinnitus frequency is retrieved via the input device.

As shown in the figure, the system may include input means such as a keyboard 207 or a computer mouse 206 by which the user or operator of the system may input information to be used during the treatment of a patient, i.e. information about the frequency, at which the patient's tinnitus perception occurs. The information received, or information derived therefrom, is advantageously stored in the storage 222. The system may also include output means, such as a computer screen 203 or a printer, by which the operator may be presented to information prior to, during and/or after the performance of a treatment of a patient.

The treatment of tinnitus perception according to the invention may be performed by a head born treatment device and preferably by a digital signal processor based device such as a digital hearing aid. When implementing the apparatus of the invention in a hearing aid, the treatment or at least a major part thereof may be performed by bringing the hearing aid into a tinnitus treatment mode. In the tinnitus treatment mode, the normal hearing aid functions of the hearing aid may advantageously be disabled as external sound hereby will not affect the tinnitus treatment.

By use of psycho-acoustical procedure we measure the affective dynamics of residual

inhibition pre-, peri- and post-treatment, thereby providing an alternative, subjective clinically controlled documentation for the measure of tinnitus perception, alternatively to the objective measure of contra-lateral evoked otoacoustic emission (EOAE) amplitude suppression effect, expressed in equivalent attenuation / dB SAL.

Tinnitus often occurs at a specific frequency or over a small frequency range and is frequently constant; however, the specific frequency or small frequency range varies from patient to patient.

Due to the fact that a preferred embodiment of the invention has been illustrated and described herein, it will be apparent to those skilled in the art that modifications and improvements may be made to forms herein specifically disclosed.

Claims:

1. Method for treating a patient for persistent tinnitus perception comprising the steps of:

- selecting an ear to be treated, said ear being subjected to tinnitus perception;
- determining the frequency, or frequency range, at which the patient's tinnitus occurs in the selected ear;
- establishing, based on the specific tinnitus frequency, or tinnitus frequency range, an acoustic stimuli signal having a frequency, or frequency range, and an intensity enabling the tinnitus to be masked, and
- intermittently affecting the ear to be treated with the acoustic stimuli signal, where stimuli periods of a first predefined duration are interspersed with inter-stimuli periods of a second predefined duration.

2. Method according to claim 1, wherein the ear to be treated is selected as the ear in which the tinnitus perception is most dominant.

3. Method according to claim 1 or 2, wherein at least one and preferably a major part or all of the said stimuli periods is/are set to be of a specific duration sufficient for obtaining residual inhibition in the patient and preferably in the range of 1 - 30 seconds and even more preferably in the range of 10-15 seconds.

4. Method according to claim 3, wherein the duration of said at least one and preferably a major part or all of the stimuli periods is determined by:

- affecting the ear to be treated with at least one acoustic test signal having a temporally defined test stimuli period and determining the duration of the test stimuli period necessary for obtaining residual inhibition in the patient; and

- setting the duration of said stimuli periods to be equal to or larger than the minimum necessary duration determined using the acoustic test signal.

5. Method according to claim 3 or 4, wherein at least one and preferably a major part or all of the said inter-stimuli periods is/are set to be of a specific duration sufficient for the patient again to perceive the tinnitus within said at least one and preferably a major part or all of the said inter-stimuli periods, preferably within 1 - 30 seconds, and even more preferably in the range of 10-15 seconds.

6. Method according to claim 5, wherein the duration of the residual inhibition obtained in the test stimuli period having said established necessary duration is determined and the duration of at least one and preferably a major part or all of the inter-stimuli periods is set to be longer or equal to the determined duration of the residual inhibition.

7. Method according to claim 5 or 6, wherein at least one and preferably a major part or all of the said inter-stimuli periods is/are set to be of a specific duration sufficient for the patient again to perceive the tinnitus for a given period of time, preferably in the range of 1-30 seconds, and even more preferably in the range of 10-15 seconds.

8. Method according to any of the claims 1-7, wherein said stimuli frequency or stimuli frequency range is set to be in the range of 0.25-2 octaves below the established tinnitus frequency or tinnitus frequency range, and even more preferably approximately half an octave below the established tinnitus frequency or tinnitus frequency range.

9. Method according to any of the claims 1-8, wherein said acoustic signal comprises a pure tone signal having a fundamental frequency equal to the stimuli frequency.

10. Method according to any of the claims 1-8, wherein the acoustic signal comprises a noise signal having a centre frequency equal to or at least substantially equal to the

determined stimuli frequency and with a band width of preferably one third of an octave.

11. Method for treating a patient for persistent tinnitus perception by intermittently affecting the ear to be treated with an acoustic signal having a predefined stimuli frequency, or stimuli frequency range, and an intensity enabling the tinnitus to be masked, wherein stimuli periods of a first predefined duration, preferably in range of 1 - 30 seconds, and even more preferably in the range of 10 - 15 seconds, are interspersed with inter-stimuli periods of a second predefined duration, preferably in the range of 1-30 seconds, and even more preferably in the range of 10 - 15 seconds.

12. System for treating a patient for persistent tinnitus perception comprising:

- a signal source, such as an electro-acoustic transducer, adapted to affect an ear to be treated with an acoustic signal;

- a storage adapted to contain stimuli signal information;

- a processor, such as a digital signal processor, adapted to, based on said stimuli signal information, intermittently affecting the ear of a patient with an acoustic stimuli signal via said signal source, where stimuli periods of a first predefined duration are interspersed with inter-stimuli periods of a second predefined duration, said stimuli signal having a frequency and an intensity enabling the tinnitus to be masked during said stimuli periods.

13. System according to claim 12 comprising an input device, such as a keyboard, adapted to receive stimuli signal information and to store the received stimuli signal information or information derived therefrom in said storage.

14. System according to one or more of the claims 12-13, said system being adapted to generate said acoustic stimuli signal wherein at least one and preferably a major part or all of said stimuli periods have a first predefined duration, preferably in the range of 1-30 seconds, and even more preferably in the range of 10-15 seconds, which is sufficient to obtain residual inhibition in the patient, and at least one and preferably a major part or all of said inter-stimuli periods have a second predefined duration, preferably in the range of 1-30 seconds, and even more preferably in the range of 10-15 seconds, being sufficient for the patient again to perceive tinnitus.

15. System according to claim 14, wherein the duration of at least one and preferably a major part or all of the inter-stimuli periods is sufficient for the patient again to perceive the tinnitus for a given period of time.

16. System according to one or more of the claims 12-15, wherein said signal source is adapted to emit a pure tone signal having a fundamental frequency equal or substantially equal to the set stimuli frequency and/or noise signal having a centre frequency equal or substantially equal to the set stimuli frequency and a band width of preferably one third of an octave.

17. System according to any of the claims 12-16, characterised in that the system is built into a hearing aid.

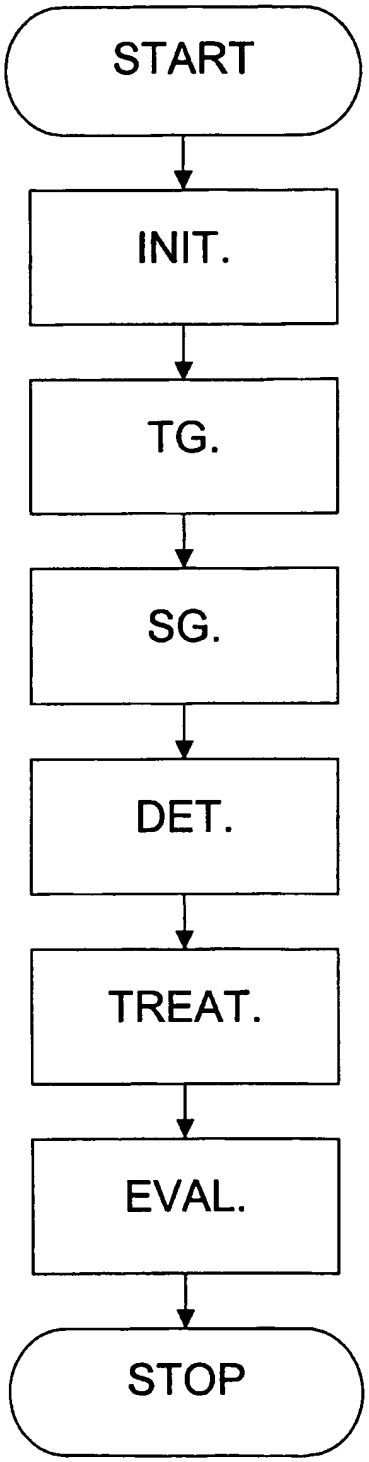

Fig. 1

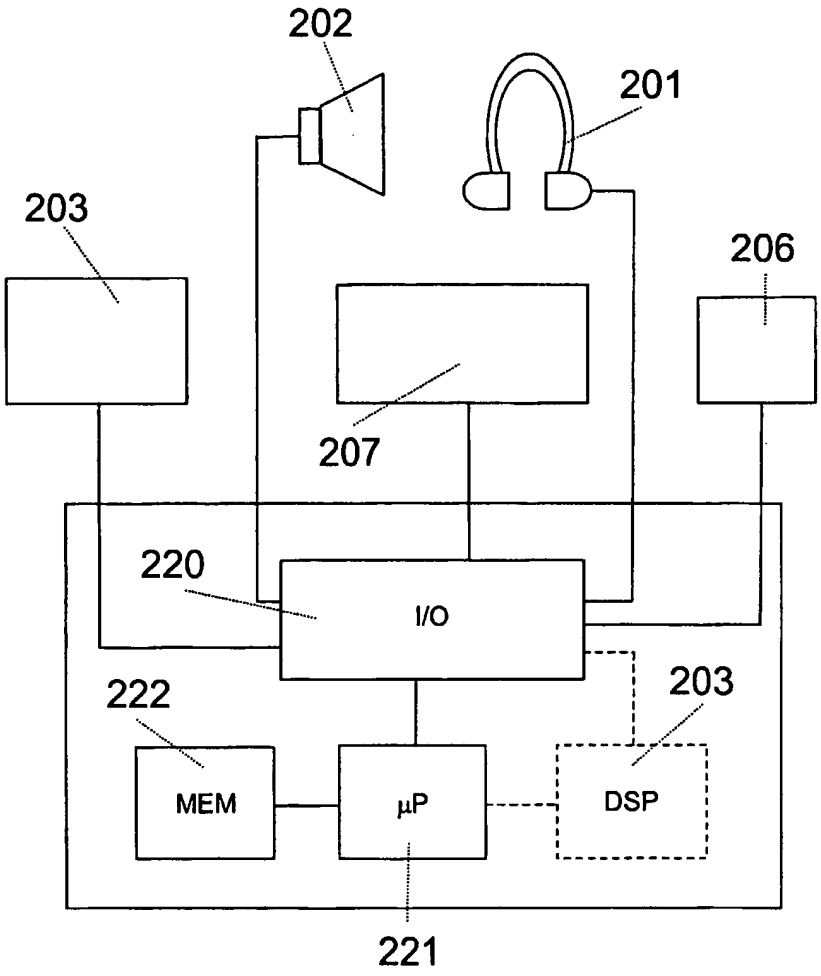

Fig. 2

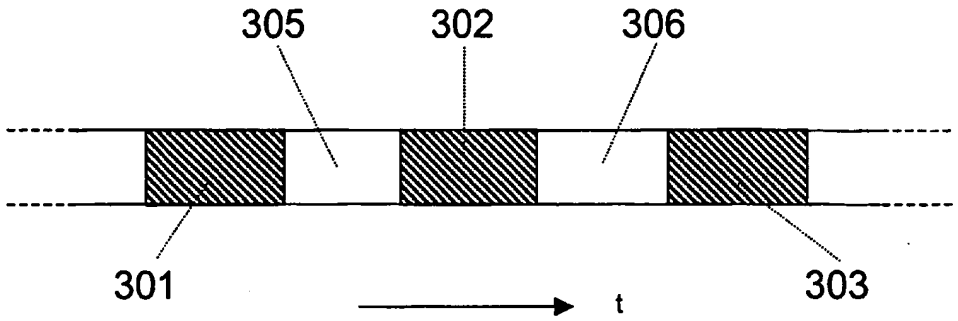

Fig. 3

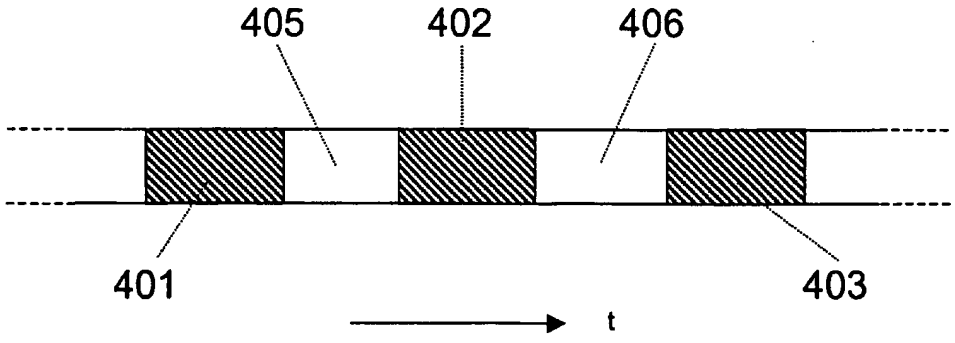

Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK 02/00330

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 H04R25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 H04R A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 155 971 A (MERZENICH MICHAEL M ET AL) 5 December 2000 (2000-12-05)	1,2, 8-10,12, 13,16
	column 1, line 6-9	
Y	column 2, line 37-59	17
	column 6, line 31 -column 10, line 24	
A	column 10, line 45 -column 12, line 42	3-7,11, 14,15

Y	US 5 403 262 A (GOOCH TIMOTHY D) 4 April 1995 (1995-04-04)	17
	column 1, line 59 -column 2, line 29	
A	column 3, line 19 -column 8, line 29	1-16

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 August 2002	19/08/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zanti, P

Form PCT/ISA/210 (second sheet) (July 1992)

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